

**ANDERSON EXHIBIT 7A**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
<u>Ex Rel</u>	)	
VEN-A-CARE OF THE	)	CIVIL ACTION NO. 00 CV 10698
FLORIDA KEYS, INC.,	)	MEL
a Florida Corporation,	)	
by and through its principal	)	
officers and directors,	)	
ZACHARY T. BENTLEY and	)	
T. MARK JONES,	)	
	)	
Plaintiff,	)	
v.	)	
	)	
ABBOTT LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

**COMPLAINT FOR VIOLATIONS OF  
THE FALSE CLAIMS ACT, 31 U.S.C. §3729, et seq.  
AGAINST ABBOTT LABORATORIES, INC.**

VEN-A-CARE OF THE FLORIDA KEYS INC. ("VEN-A-CARE" or the "Relator") brings this fraud action on behalf of the United States and on the Relator's own behalf, against ABBOTT LABORATORIES, INC. ("Abbott") to recover losses sustained by the Medicaid Program arising out of the DEFENDANT'S violations of the Federal False Claims Act ("False Claims Act" or the "Act") 31 U.S.C., §§3729-3732. Over the course of several years, Abbott reported inflated pharmaceutical prices that it knew Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products. Abbott's actual sales prices, the prices generally and currently available in the marketplace, for its pharmaceutical products were far less than the prices reported by Abbott. By

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knowingly reporting inflated prices - often two times higher than prices generally and currently available in the marketplace - Abbott ensured its customers received inflated reimbursement and profits from Medicaid. Abbott then used the public fisc as a marketing tool, actively promoting government-funded "spreads" between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. These efforts allowed Abbott to increase its profits by boosting sales for its drugs.

### **I. NATURE OF ACTION**

1. Ven-A-Care brings this action on behalf of the United States to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief.

2. Ven-A-Care bases its claims on Abbott having submitted and caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. §3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Within the time frames detailed below, Abbott engaged in a fraudulent scheme that caused the Medicaid Program to pay excessive reimbursement to Abbott's customers; e.g., pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians (hereafter referred to collectively as "Customers"). In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in paragraph 33 below) to several price reporting compendia that the Medicaid Program relied upon to set

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reimbursement rates for Abbott's customers. A chart setting out examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit A**. Abbott knew that the Medicaid Program relied on Abbott's reported prices to the pricing compendia to set reimbursement rates for claims submitted for Abbott's drugs. Abbott then sold the drugs for far lower prices, and marketed to existing and potential Customers the government-funded "spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to boost its sales and profits.

4. Abbott knew that its false price reporting and marketing efforts would cause its Customers to submit claims for fraudulently inflated Medicaid reimbursement.

5. Abbott's fraudulent scheme to induce Customers to purchase its products by ensuring that Medicaid reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. §1320a-7b(b) and numerous state laws.

6. To get fraudulent claims paid by the Medicaid Program, Abbott also routinely made false statements by reporting these same fraudulently inflated prices directly to the states. These statements violated the FCA and various state laws.

## II. JURISDICTION

7. Jurisdiction is founded upon the Federal False Claims Act, 31 U.S.C. §3729-32, specifically 31 U.S.C. §3730, and also 28 U.S.C. §§1331, 1345.

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8. Ven-A-Care's claims against Abbott in this matter were filed on February 15, 2001 in the District of Massachusetts.<sup>1</sup> The claims against Abbott were severed from the main action in anticipation of the United States' declination and in anticipation of the Relator litigating those declined claims. After severance, the Relator filed this Amended Severed Complaint pursuant to the Court's Order dated July 31, 2007.

9. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345. The Court may exercise personal jurisdiction over Abbott pursuant to 31 U.S.C. §3732(a) because Abbott resides or transacts business in the District of Massachusetts.

10. The Relator has standing to bring and has brought this action on behalf of itself and the United States pursuant to 31 U.S.C. §3730.

### III. VENUE

11. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Abbott resides or transacts business in this District.

### IV. PARTIES

12. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care's principal officers and directors during the relevant time period

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<sup>1</sup>This case originated in the District of Massachusetts as Case No.00-CV-10698, the *qui tam* matter filed by Ven-A-Care under seal in front of United States District Judge Lasker.

have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider.

13. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims.

Ven-A-Care brought this action against Abbott on behalf of itself and the United States.

14. The Relator, Ven-a-Care became aware of Abbott's false claim scheme alleged herein due to its position as an industry insider. The Relator commenced its *qui tam* action against Abbott for the drugs at issue based upon its industry insider information. Ven-A-Care, as a pharmacy, has access to pricing information such as wholesaler and GPO catalogues and computer programs revealing the prices generally and currently available in the marketplace, but not known to the general public or the Government. Ven-A-Care, as an industry insider, discovered that Abbott created huge profit spreads on the Drugs at issue and that the Drugs were reimbursed by Medicaid at amounts that substantially, and in some cases, exceeded two or three times the cost of the drug. Ven-A-Care's principals were aware that Medicaid reimbursed for drugs at amounts that were intended to be based on an estimation of cost and not provide for huge windfall profits at the Government's expense.

15. The United States has declined to join the prosecution of this action, but remains a party to this action pursuant to 31 U.S.C. § 3730(c)(3). The United States

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has requested that it be supplied with copies of all pleadings filed in the action and copies of all deposition transcripts.

16. Defendant Abbott is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, Abbott has transacted business throughout the United States, selling and distributing its drugs, including but not limited to those identified in this Complaint, to purchasers within this District.

## V. THE LAW

### A. The False Claims Act

17. The FCA provides in pertinent part, that:

- (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government

\* \* \*

is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

\* \* \*

- (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.



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18. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to \$5,500 to \$11,000 for violations occurring on or after September 29, 1999.

**B. The Federal Anti-Kickback Statute**

19. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of Medicare and Medicaid. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

20. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

(b) Illegal remuneration

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind-

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or



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service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to \$50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

## **VI. THE MEDICAID PROGRAM**

### **A. THE PROGRAM**

21. Medicaid was created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

22. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

### **B. FUNDING**

23. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

24. The Medicaid programs of all states reimburse for prescription drugs.

25. The United States Government, under the Secretary of the United States Department of Health and Human Service, is required to pay to each state, for each calendar quarter, an amount equal to the Federal Medical Assistance Percentage ("FMAP") of the total amount expended by the state during the quarter as medical assistance under the state Medicaid plan pursuant to 42 U.S.C. § 1396b(a)(1).

26. The federal portion of States' Medicaid payments, Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. The federal portion consists of a minimum of 50% up to a maximum of 83%. For example, Florida's FMAP contributed by the United States in the fiscal year October 1, 2003 to September 30, 2004 was 58.93%.

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27. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

28. Each State Health Plan must, in part, provide a formula for payment of reimbursement claims for prescription drugs, and each state's plan must be approved by the Secretary of HHS. The formula determines the reimbursement amount the state plan will pay for each drug manufactured by each manufacturer whose prescription drugs qualify for Medicaid reimbursement, based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. 42 CFR §447.331. Under certain circumstances, the federal Center for Medicare and Medicaid Services ("CMS") may establish a "Federal Upper Limit," binding on all state plans, on the allowable reimbursement for a particular drug.

29. The states' methodologies for arriving at a provider's Estimated Acquisition Cost ("EAC") for each covered drug, as required by 42 CFR §447.331, must be approved by the Secretary of HHS.

30. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

31. To claim its FMAP payment, each state must submit a report to the United States Secretary of Health and Human Services reflecting its anticipated Medicaid expenses for the quarter. The Secretary is required to estimate the state's FMAP

entitlement for the quarter, based on the state's report and such other investigation as the Secretary may find necessary, and pay that amount to the state in such installments as the Secretary may determine, adjusted for any overpayments or underpayments in prior quarters. 42 U.S.C. § 1396b(d)(1), (2A). The Secretary's determination of a state's FMAP entitlement obligates any appropriations available for payments to the state. 42 U.S.C. § 1396b(d)(4).

32. Abbott knowingly reported false, inflated price and cost data for the specified drugs to the pharmaceutical pricing compendia relied on by the states, or directly to the states, or both, and therefore caused claims submitted by each state to officers and employees of the UNITED STATES for FMAP to be greater than they would have been but for the DEFENDANTS' false price representations. As a result, Abbott caused the United States to expend FMAPs in amounts greater than would have been expended, but for the Defendants' false reports of price and cost data, and thus caused injury to the federal fisc.

**C. DRUG REIMBURSEMENT**

33. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case (collectively referred as the "Drugs") are listed below:

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1	Erythromycin Ethylsuccinate Tab 400 mg	00074-2589-13
2	Erythromycin Ethylsuccinate Tab 400 mg	00074-2589-53
3	ERYTHR ETH LIQ 200mg/5ml	00074-3747-16
4	ERYTHR ETH LIQ 400mg/5ml	0007-43748-16
5	E.E.S. 400 FILM	00074-5729-11
6	E.E.S. 400 FILM	00074-5729-13
7	E.E.S. 400 FILM	00074-5729-19
8	E.E.S. 400 FILM	00074-5729-53
9	ERYTHR BSE TAB 500mg	00074-6227-13
10	ERYTHROMYC DR 250mg CAP	00074-6301-13
11	ERYTHROMYC DR 250mg CAP	00074-6301-53
12	Ery-tab E/c Ud 250 Mg 100's	00074-6304-11
13	Ery-tab E/c 250 Mg 100's	00074-6304-13
14	Ery-tab E/c 250 Mg 30's	00074-6304-30
15	ERY-TAB 250MG E	00074-6304-40
16	ERY-TAB 250MG E	00074-6304-53
17	EES 200 Susp. 100ml	00074-6306-13
18	EES 200 Liq 200 Mg/5 ml	00074-6306-16
19	Erythromycin Stearate 500 Mg Tab 100's	00074-6316-13
20	Ery-tab 333 mg	00074-6320-11
21	Ery-tab 333 mg	00074-6320-13
22	Ery-tab 333 mg	00074-6320-30
23	Ery-tab 333 mg	00074-6320-53
24	Ery-tab 500 Mg u	00074-6321-11
25	Ery-tab 500 Mg e	00074-6321-13
26	ERYTHR BSE TB 250mg	00074-6326-11
27	Erythromycin Base 250 Mg Tab 100's	00074-6326-13
28	Erythromycin Base 250 Mg Tab 500's	00074-6326-53
29	ERYTHR STE 250mg TAB	00074-6346-19
30	Erythromycin Stearate 250 Mg Tab 100's	00074-6346-20
31	Erythromycin Stearate Ud 250 Mg Tab 100's	00074-6346-38
32	ERYTHR STE 250mg TAB	00074-6346-41
33	Erythromycin Stearate 250 Mg Tab 500's	00074-6346-53
34	E.E.S. GRAN 200	00074-6369-02
35	E.E.S. GRAN 200	00074-6369-10
36	E.E.S. 400 LIQ	00074-6373-13
37	EES 400 Liq 400 Mg/5 ml	00074-6373-16
38	EES/sulfisoxazole 200 Mg, 100 ml	00074-7156-13
39	EES/sulfisoxazole 200 Mg 150 ml	00074-7156-43
40	EES/sulfisoxazole 200 Mg 200 ml	00074-7156-53
41	Pediazole Susp	00074-8030-13
42	Pediazole Susp	00074-8030-43

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43 Pediazole Susp

00074-8030-53

34. Drug manufacturers, such as Abbott, have not typically submitted claims for reimbursement to federal health care programs. Instead, Abbott marketed its products to its Customers, who then purchased the products either directly or through wholesalers based on a price the Customers negotiated with Abbott. In addition to using wholesalers, Customers also purchased Abbott products through group purchasing organizations ("GPO"), who negotiated prices on behalf of Abbott's Customers.

35. Abbott's Customers submitted claims for payment for Abbott products to Medicaid after dispensing or administering Abbott drugs.

36. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

37. Each of the claims at issue is a false claim, in part, because each was supported by, and the reimbursement amount was determined from, the false and misleading price information provided by Abbott in connection with the Drugs. The claims at issue in this action are all claims for reimbursement submitted to Medicaid by or on behalf of Providers that sought and received payments in excessive amounts because of Abbott's false price reports. The claims at issue number in the tens of thousands and were submitted by thousands of Providers nationwide throughout the relevant time period of the Complaint. Each claim is in the possession of the state Medicaid programs.

38. During the relevant period, Abbott usually reported prices to various price



publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

39. The reimbursement amounts for claims submitted by Abbott's Customers for the drugs at issue in this Complaint were directly influenced by Abbott's false price representations. The information contained in the published pricing compendia was used by most third party payor insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. Abbott knew of the impact of its price representations on government reimbursement on claims submitted by its Customers for its drugs.

40. No governmental payor knew of or sanctioned Abbott's conduct as set forth in this Complaint; i.e., its deliberate manipulation of its published prices for certain of its products to induce its Customers to purchase those products.

#### **D. REIMBURSEMENT FORMULAS**

41. When reimbursing for drugs, the Medicaid Program's goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

42. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on



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the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

43. The states' methodology for arriving at EAC includes:

- A. discounting a percentage off of the Average Wholesale Price ("AWP");
- B. adding a percentage to the Wholesale Acquisition Cost ("WAC"); and/or,
- C. requiring the drug companies to certify prices directly in writing to the Medicaid program.

44. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then dispenses or administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

42. While the majority of states use published AWP's to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

45. The AWP's and WAC's relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the Red Book